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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
09/25/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/724,826	<b>Applicant(s)</b> SIMONNET ET AL.	
	<b>Examiner</b> Carlic K. Huynh	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-53 is/are pending in the application.
- 4a) Of the above claim(s) 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02 December 2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks filed on June 29, 2007 is acknowledged.

#### ***Status of the Claims***

1. Claims 25-53 are pending in the application, with claims 44-53 having been withdrawn from consideration, in response to the Non-Final Rejection submitted on March 29, 2007. Claims 1-24 have been cancelled in a Preliminary Amendment filed on December 2, 2003. Accordingly, claims 25-43 are being examined on the merits herein.

#### ***Information Disclosure Statement***

The Information Disclosure Statement submitted on December 2, 2003 is acknowledged.

#### ***Response to Arguments***

2. Applicant's arguments, see "Remarks" filed on June 29, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 25-43 has been fully considered and are found persuasive. The Applicants have argued that the references "Ribier II, Matsumoto, Valdivia, and Nguyen" do not teach the instant invention of oil globules that are free from a lamellar liquid crystal coating. Thus the "Rejections under 35 U.S.C. § 103" are withdrawn in light of the arguments.
2. Applicant's arguments, see "Remarks" filed on June 29, 2007, with respect to "Obviousness Double Patenting (ODP) Rejections" to claim 25 have been fully considered and are found persuasive. Ribier et al. (U.S. Patent 5,658,575), Ribier et al. (U.S. Patent 5,753,241),

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Cervantes et al. (U.S. Patent 5,925,341), Ribier et al. (U.S. Patent 5,925,364), Ribier (U.S. Patent 6,066,328), Simonnet (U.S. Patent 6,120,778), Simonnet et al. (U.S. Patent 6,126,948), Simonnet (U.S. Patent 6,274,150), Simonnet et al. (U.S. Patent 6,375,960), Simonnet et al. (U.S. Patent 6,413,527), Simonnet et al. (U.S. Patent 6,464,990), Simonnet et al. (U.S. Patent 6,541,018), Verite et al. (U.S. Patent 6,562,356), L'Alloret et al. (U.S. Patent 6,998,426), Aubrun et al. (U.S. Patent Application 2003/0206955 or 09/860,466), Simonnet et al. (U.S. Patent Application No. 2004/0009131 or 10/426,630), Simonnet (U.S. Patent Application No. 2004/0258644 or 10/823,715), Douin et al. (U.S. Patent Application No. 2005/0226842 or 11/097,371), L'Alloret et al. (U.S. Patent Application No. 2006/0030655 or 11/248,285), and Tank et al. (U.S. Patent Application No. 2007/0027034 or 11/495,228) are not obvious over the instant invention. Thus the ODP Rejection to claim 25 is withdrawn.

3. Applicant's arguments, see "Remarks" filed on June 29, 2007, with respect to "Objection to Oath/Declaration" have been fully considered and are not found persuasive. Applicants have argued that "French citizenship properly identifies the inventors as being from France". This argument is not found persuasive because "French" is a language and not a country. Thus the Objection to Oath/Declaration remains.

4. Applicant's arguments with respect to claims 25-43 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to amended claims 25-43 are used herewith.

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***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it does not identify the citizenship of each inventor. The citizenship of each inventor is listed as "French". French is not a proper country. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 25-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (US 5,753,241), in view of Tabibi et al. (US 5,130,122) as evidenced by Nguyen et al. (US 6,669,849).

Ribier et al. teach an oil-in-water nanoemulsion, in which the oil globules are less than 100 nm, and contain an amphiphilic lipid component (abstract). The amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18). The oil can be a silicone oil, namely decamethylcyclopentasiloxane, which has a molecular weight of 370.78 (column 3, line 47). The oil can also be Jojoba oil, which contains 36 to 46 carbons, and

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has a molecular weight of at least 432 (column 5, example 1; and wikipedia.org). Jojoba oil makes up 50% of the oils having a molecular weight greater than 400 (column 5, example 1).

Furthermore, Ribier et al. teach ionic amphiphilic lipids in the nanoemulsions, which can be alkaline salts of dicetyl and dimyristyl phosphate, alkaline salts of cholesterol sulphate, alkaline salts of cholesterol phosphate, sodium salts of phosphatidic acid, phospholipids, or alkylsulfonic derivatives (columns 2, lines 57-65; and column 3, lines 1-3). The ionic amphiphilic lipids are from 2 to 10% by weight (column 3, line 13).

Ribier et al. also teach emulsions that contain additives to improve the transparency of the formulation, such as lower alcohols and are 5 to 20% by weight (column 3, lines 49-51, 53, and 62).

Ribier et al. also teach the nanoemulsion for topical use such as a cosmetic or dermatopharmaceutical composition and for use on the eyes (column 4, lines 45-49). Since the nanoemulsion of Ribier et al. is for ophthalmic use (e.g. use on the eyes), it would be obvious that such a nanoemulsion contains an ophthalmic vehicle.

Ribier et al. do not teach nanoemulsions containing the surfactants herein and the turbidity of the nanoemulsion.

Tabibi et al. teach a submicron emulsion of an adsorptive oil that contains surfactants (column 6, lines 58-59 and 62). The adsorptive oil may be from vegetable oils, mineral oils, or animal oils (column 2, lines 33-35). The submicron emulsions are less than about 0.3 microns in diameter (column 4, lines 13-15).

Tabibi et al. do not specifically name surfactants and thus it would be obvious that the surfactants of Tabibi et al. may include sucrose distarate as recited in claims 30 and 31 and other surfactants that are solids at a temperature of less than or equal to 45°C.

As evidenced by Nguyen et al., Nguyen et al. disclose a process for the removal of dissolved organic carbon from water (abstract). The organic carbon compounds in various water samples were coagulated, by addition of a coagulant, to form a floc, which can then be physically removed (column 1, lines 29-32). The turbidity of water samples where the floc size is 1-2 mm is 3.6 NTU (column 13, Table 2). Thus, the nanoemulsions of less than 100nm in the instant application are reasonably expected to have a turbidity measurement of 60 to 600 NTU as recited in instant claim 26.

Accordingly, absent the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the nanoemulsions of Ribier et al. to contain a surfactant because the submicron emulsions of Tabibi et al. contain a surfactant and according to Tabibi et al., submicron emulsions or nanoemulsions contain a surfactant.

The motivation to combine the nanoemulsion of Ribier et al. to the submicron emulsions of Tabibi et al. is that the submicron emulsions of Tabibi et al. contain a surfactant.

Regarding the amount of surfactant as recited in the instant claims 25 and 27-28, it is noted that Tabibi et al. teach submicron emulsions of adsorptive oils contain surfactants but the concentration of such surfactants were not disclosed (column 6, lines 58-59 and 62). Thus Tabibi et al. do teach the presence of a surfactant, which closely meets the amount of surfactant set forth in instant claim s 25 and 27-28. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount

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of surfactant provided in a composition, according to the guidance set forth in Tabibi et al., to provide a composition having desired amount of surfactant. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the ratio by weight of the amount of oily phase to the amount of surfactant as recited in instant claim 28, Ribier et al. teach the amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18). Tabibi et al. teach submicron emulsions of adsorptive oils contain surfactants but the concentration of such surfactants were not disclosed (column 6, lines 58-59 and 62). Since Ribier et al. teach the amount of oil ranges from 5 to 30% by weight and Tabibi et al. teach the presence of surfactants, it would be obvious that the amount of surfactant present may yield a ratio of amount of oily phase to the amount of surfactant of 3 to 6 as recited in instant claim 28.

### ***Double Patenting***

#### **Obviousness-Type**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).



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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 25 and 42-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 17-19 of Simonnet et al. (US 6,335,022).

Simonnet et al. teach a nanoemulsion comprising oil globules of less than 100 nm, a surfactant of sorbitan fatty esters that is a solid at less than or equal to 45°C, an oil having a molecular weight greater than 400, and the ratio by weight of the amount of oily phase to the amount of surfactant is 2 to 10 (column 2, lines 25-44).

Simonnet et al. do not mention the nanoemulsions contain a lamellar liquid crystal coating and thus it would be obvious the nanoemulsions of Simonnet et al. are free of a lamellar liquid crystal coating.

The nanoemulsion may be made into a composition for topical use and as an ophthalmic vehicle (column 10, lines 17-20).

Sorbitan is well known in the art as a sugar and thus it would be obvious that sorbitan may be the sugar surfactant of the instant invention.

8. Claims 25 and 42-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 30-31 of Sonnevile et al. (US 6,419,946) and over claims 1, 19, 25, 42, and 48 of Simonnet et al. (US 6,541,018).

Sonneville et al. teach a nanoemulsion comprising oil globules of less than 100 nm, a surfactant of glycerol mixed with esters of a fatty acid or a fatty alcohol, an oil having a

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molecular weight greater than 400, and the ratio by weight of the amount of oily phase to the amount of surfactant is 2 to 10 (column 2, lines 20-31). The nanoemulsion may be made into a composition for topical use and as an ophthalmic vehicle (column 10, lines 24-27). The surfactant was not disclosed as being a solid at less than or equal to 45°C and thus it would be obvious that the surfactant may be a solid at less than or equal to 45°C. It is well known in the art that glycerol is a sugar alcohol and thus it would be obvious that glycerol may be the sugar surfactant of the instant invention.

Simonnet et al. teach a nanoemulsion comprising oil globules of less than 100 nm, at least one glycerol fatty acid surfactant that is a solid at less than or equal to 45°C, an oil having a molecular weight greater than 400, and the ratio by weight of the amount of oily phase to the amount of surfactant is 2 to 10 (column 2, lines 20-30). The nanoemulsion may be made into a composition for topical composition and an ophthalmic vehicle (column 9, lines 53-54). It is well known in the art that glycerol is a sugar alcohol and thus it would be obvious that glycerol may be the sugar surfactant of the instant invention.

Sonneville et al. and Simonnet et al. do not mention the nanoemulsions contain a lamellar liquid crystal coating and thus it would be obvious the nanoemulsions of Sonnevile et al. and Simonnet et al. are free of a lamellar liquid crystal coating.

9. Claims 25 and 42-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 17-18 of Simonnet et al. (US 6,461,625).

Simonnet et al. teach a nanoemulsion comprising oil globules of less than 100 nm, a surfactant of alkoxylated alkenyl succinates of glucose, an oil having a molecular weight greater

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than 400, and the ratio by weight of the amount of oily phase to the amount of surfactant is 2 to 10 (abstract).

Simonnet et al. do not mention the nanoemulsions contain a lamellar liquid crystal coating and thus it would be obvious the nanoemulsions of Simonnet et al. are free of a lamellar liquid crystal coating.

The nanoemulsion may be made into a composition for topical use and as an ophthalmic vehicle (abstract; and column 9, lines 29-30).

The surfactant was not disclosed as being a solid at less than or equal to 45°C and thus it would be obvious that the surfactant may be a solid at less than or equal to 45°C.

It is well known in the art that glucose is a sugar and thus it would be obvious that glycerol may be the sugar surfactant of the instant invention.

### ***Conclusion***

10. No claims are allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

  
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